SEP 14 2004

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510(k) Summary
Summary of Safety and Effectiveness Information

Sponsor:
Twin Star Medical, Inc.
914 South 8th Street
Mail Code 860c
Minneapolis, Minnesota 55404
Tele: 763.576.5172
Fax: 763.576.9273

Device Name:
Twin Star Compartment Monitoring and Fluid Collection Catheter System

Device Classification:
Class II – Monitor, Pressure, Intracompartmental

Device Description:
The Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter System consists of two major components i.e., an Introducer and an indwelling Catheter. The Introducer consists of tear-away plastic sheath placed over a stainless steel trocar. The Introducer provides an access to the targeted muscle compartment to facilitate the placement of the indwelling Pressure Monitoring and Fluid Collection Catheter. The indwelling Catheter is designed to monitor intramuscular compartment pressure as well as provide a means to sample interstitial fluid for laboratory analysis. The indwelling Catheter is designed for use up to 24 hours. The Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter System is designed to be used with currently available clinical equipment including a vacuum pump, infusion pump, pressure transducer and monitor.

Indications:
The Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter System is intended for the immediate or continuous measurement of intracompartmental pressures and the withdrawal of fluid for subsequent analysis. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome.

Substantial Equivalence:
Documentation has been provided which demonstrates that the Twin Star Compartment Syndrome Pressure Monitoring and Fluid Collection Catheter System is substantially equivalent to other legally marketed devices such as the Stryker Intra-Compartment Pressure Monitor System. Comparison testing during animal and human clinical studies has confirmed the equivalence of the Twin Star Compartment Syndrome Pressure Monitoring and Fluid Collection Catheter System with the predicate system to measure intracompartment pressure in an animal model and a human clinical study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Twin Star Medical, Inc.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004

SEP 14 2004

Re: K041771
Trade/Device Name: Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter System
Regulatory Class: Unclassified
Product Code: LXC
Dated: June 22, 2004
Received: June 30, 2004

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): #041771

Device Name:
Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter System

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K041771